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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,998	01/04/2001	Ernst H. Rinderknecht	P0941C1D1C1	4682

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,998

Applicant(s)

RINDERKNECHT ET AL

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The request filed on 9/30/04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/754998 is acceptable and a RCE has been established. Claims 28 and 30 are pending and are currently under prosecution. An action on the RCE follows.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. Claim 30 has been amended and claim 29 has been canceled.
4. The following Office Action contains NEW GROUNDS of rejections.

Rejections Withdrawn

5. The rejection of claim 30 under 35 USC 102(b) as being anticipated by Neblock et al is withdrawn in view of the amendments to the claims.
6. The rejection of claims 28 and 30 under 35 USC 103(a) as being unpatentable over Neblock et al and further in view of Shalaby et al is withdrawn in view of the amendments to the claims.

The following are NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

7. Claims 28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 28 and 30 are indefinite because claim 30 recites "antibody fragment comprising incorrectly disulfide linked light and heavy chains" and "antibody fragment comprising correctly disulfide linked light and heavy chains" and it is unclear if the fragments are of the same type. For example are the incorrectly disulfide fragments Fab fragments and the correctly disulfide fragments F(ab')₂ fragments or other combinations or are the fragments the same type?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter (US Patent 5,648,237, with priority to 9/91).

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The claims recite a composition comprising a physiologically acceptable carrier and a mixture of antibody fragment comprising incorrectly disulfide linked light and heavy chains and antibody fragment comprising correctly disulfide linked light and heavy chains wherein the purity of the correctly disulfide fragment is at least about 95% and is a Fab' fragment and the antibody fragment binds p185HER2.

Carter teach a composition comprising in a physiological carrier (see column 7, lines 40-61) a Fab'-SH that binds p185HER2 with the light and heavy chain cysteine residues that ordinarily participate in interchain bonding being present in their native form that is substantially free (greater than 90 mole percent) of Fab' fragments wherein the heavy and light chains have been reduced so as not to be present in their native state, formation of aberrant disulfides (see column 8, lines 47-60). Therefore, Carter teach correctly disulfide linked Fab'-SH fragment and the fragment is greater than about 90% pure and the mixture contains incorrectly disulfide linked fragments. Since the claims recite "antibody fragments comprising" and the antibody fragment is from a Fab' fragment, the Fab'-SH meets the limitation.

Conclusion

10. No claim is allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30

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am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER